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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/521,537 | 01/14/2005 | Francesca Dionigi | 006332.00026 | 8777 |
| 28827 | 7590 | 08/10/2006 | EXAMINER | |
| GABLE & GOTWALS | | | | SCHELL, LAURA C |
| 100 WEST FIFTH STREET, 10TH FLOOR | | | | ART UNIT |
| TULSA, OK 74103 | | | | PAPER NUMBER |
| | | | | 3767 |

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/521,537 | DIONIGI, FRANCESCA | |
| | Examiner Laura C. Schell | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/14/05</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: There is a reference number missing in Fig. 9 between 51b and 38a. It appears it should be 38c next to the line without the reference number. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowles et al. (US Patent No. 5,989,237) in view of Cloyd (US Patent No. 3,916,894). Fowles discloses the device substantially as claimed including an activation head (Fig. 4, 116) open at one end (140) thereof and closed by a pierceable membrane (directly below 73) at another end thereof; a needle shield (40) closed at one thereof (58) and open at a base (46 and 71) thereof, said base fitting and sliding in a rail (112) of said activation head; a needle (34) having a double-pointed cannula secured to a hub (71) disposed inside said rail of said activation head; an activation indicator on said rail of said activation head for indicating an initial resting position of said hub of said cannula in said activation head in which said pierceable membrane is intact; a needle shield (42) slidable inside said activation head from said initial resting position to a final activation position (Fig. 3) for acting on said hub and sequentially piercing said pierceable membranes with said inner point of said needle and connecting said cannula to said reservoir or said vial.

Fowles further discloses two retainers (46) for stopping said needle hub before activation and for locking said needle hub in position after activation (Fig. 3, 122). Fowles also discloses the needle shield having a thicker ring (56) acting as a stop against a top of said activation head during activation. Fowles further discloses the activation head having an inner narrower diameter (71) defining a stop for allowing said cannula to pass while stopping said hub. Fowles further discloses having a flange (118) to grip the device during operation. Fowles further discloses the activation head being stiffened at said base by at least one radial flap (88). Fowles also disclose the

activation head having a smooth internal surface (107) facilitating sliding of said needle hub (71) by pressing upon said needle shield (Fig. 3).

Fowles, however, does not disclose a sliding plunger within a rigid vial. Cloyd discloses a rigid vial (Fig. 1, 12) having a reservoir containing the drug and having a sliding plunger (15) hermetically sealing said vial, said plunger adapted for attachment to said another end of said activation head (plunger attaches to (8)) for making contact between a pierceable membrane of said plunger (26) and the pierceable membrane of the activation head (see Fig. 4, below 73 in Fowles). Cloyd further discloses that the activation head and said plunger have complimentary threading (9 and 16). Cloyd also discloses that the plunger is made of rubber. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Fowles with the vial with sealed plunger, as taught by Cloyd, in order to provide a system which is compact and works with just two components for ease of use and assembly.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons